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[54] **METHODS AND APPARATUS FOR ELECTRICAL MICROCURRENT STIMULATION THERAPY**

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[51] **Int. Cl.**⁷ **A61N 1/32; A61N 1/36**

[52] **U.S. Cl.** **607/53; 607/68; 607/69**

[58] **Field of Search** **607/53, 66, 68, 607/69, 76**

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Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

[57] **ABSTRACT**

An apparatus for supplying an electrical signal to a body part in order to provide microcurrent stimulation therapy to the body part. The apparatus preferably comprises a first sweep wave or sweep frequency signal generator configured to generate a first sweep wave signal, a buffer amplifier circuit configured to receive the first sweep wave signal from the first sweep signal generator and amplify and buffer the sweep wave signal creating a buffered sweep wave signal. In addition, the apparatus preferably includes a current limiting circuit configured to receive the buffered sweep wave signal from the buffer amplifier circuit and limit the amount of current supplied to the body part. Finally, the apparatus preferably comprises a probe for applying the sweep wave signal to the body part. The apparatus may further comprise a second signal generator for generating a second signal which may comprise either a sweep wave signal or a non-sweep wave signal. The apparatus also will include a signal combining circuit configured to receive the first and second signals from the first and second signal generators and combine the first and second signals into a composite sweep wave signal.

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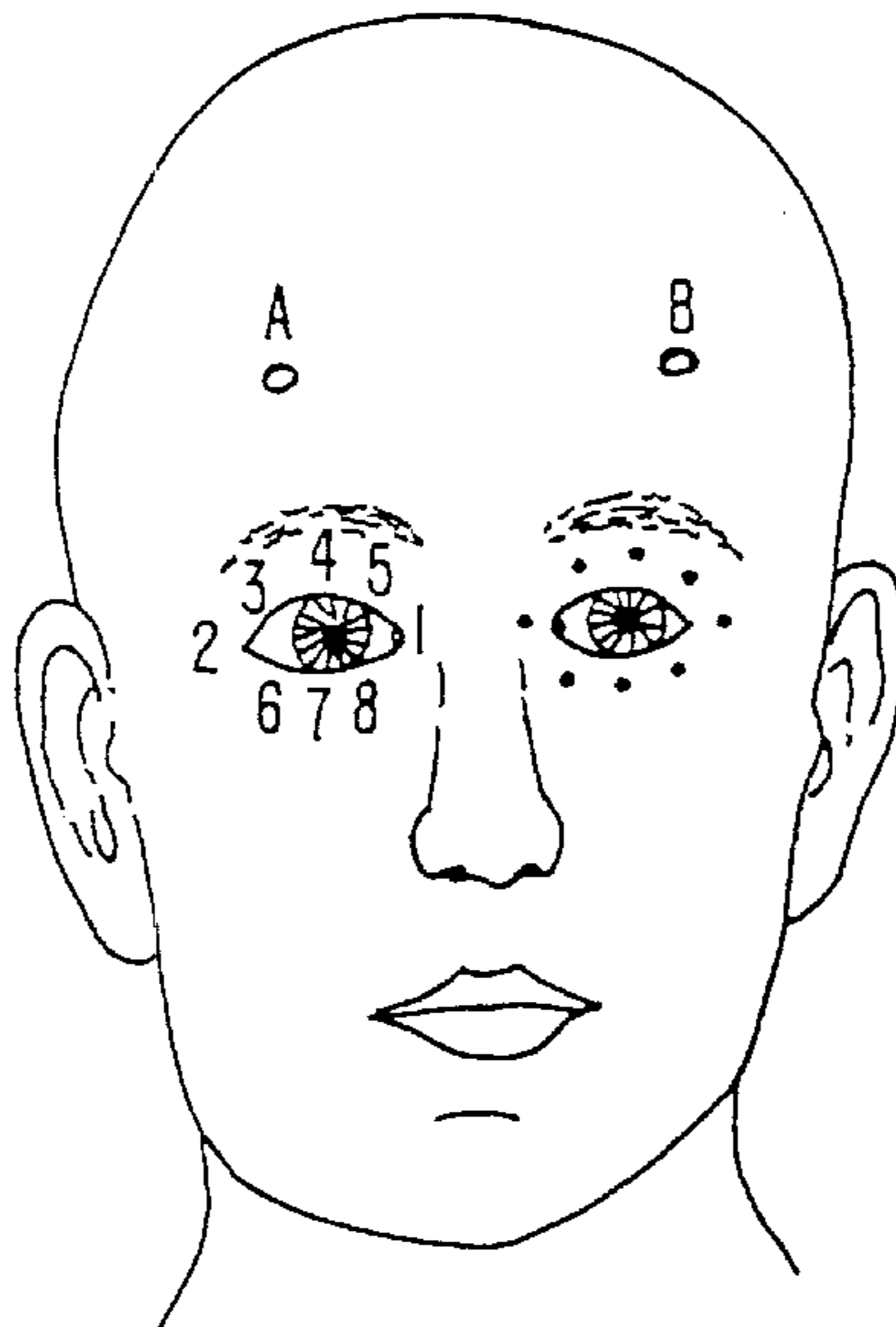
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46 Claims, 6 Drawing Sheets



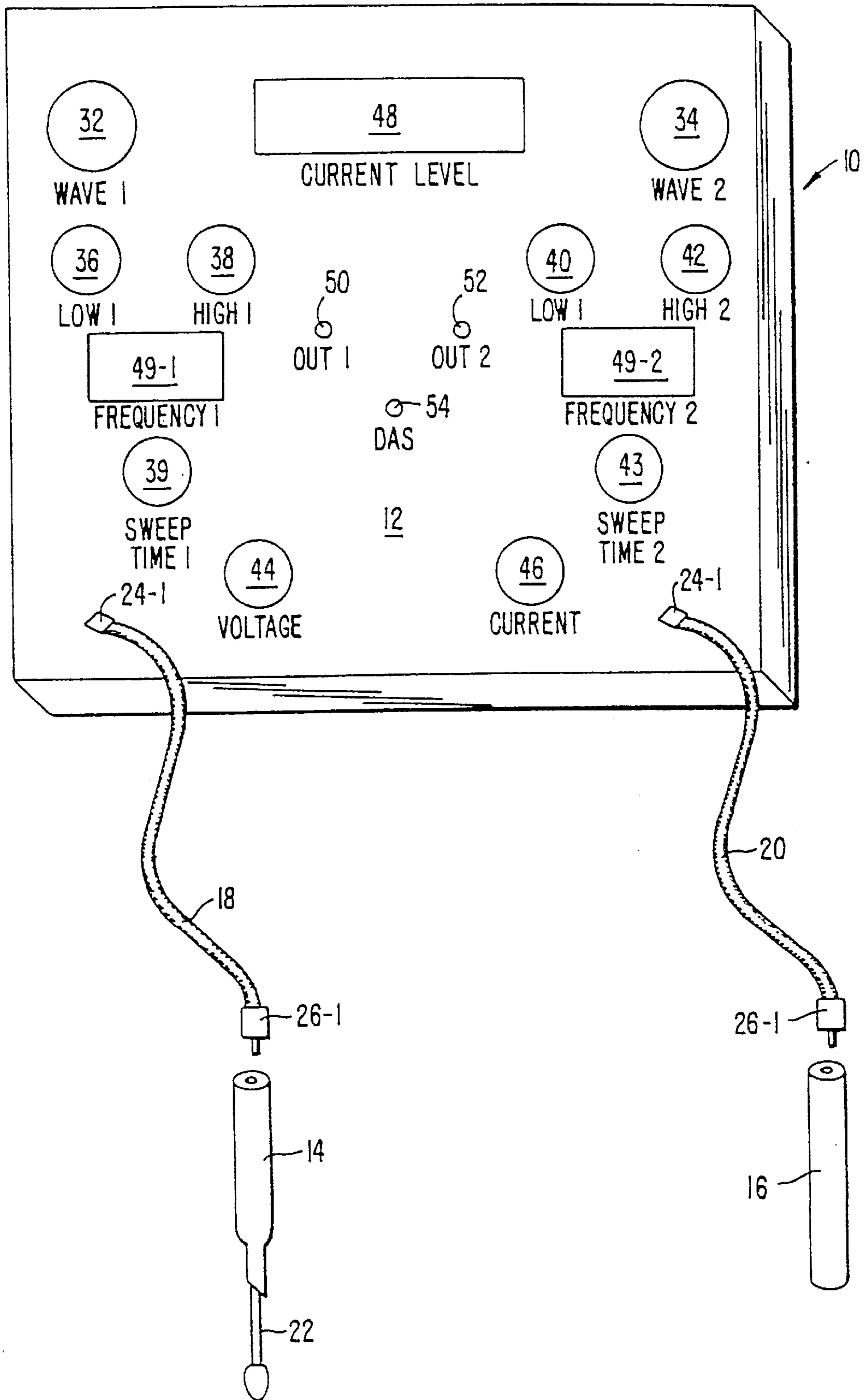


FIG. 1.

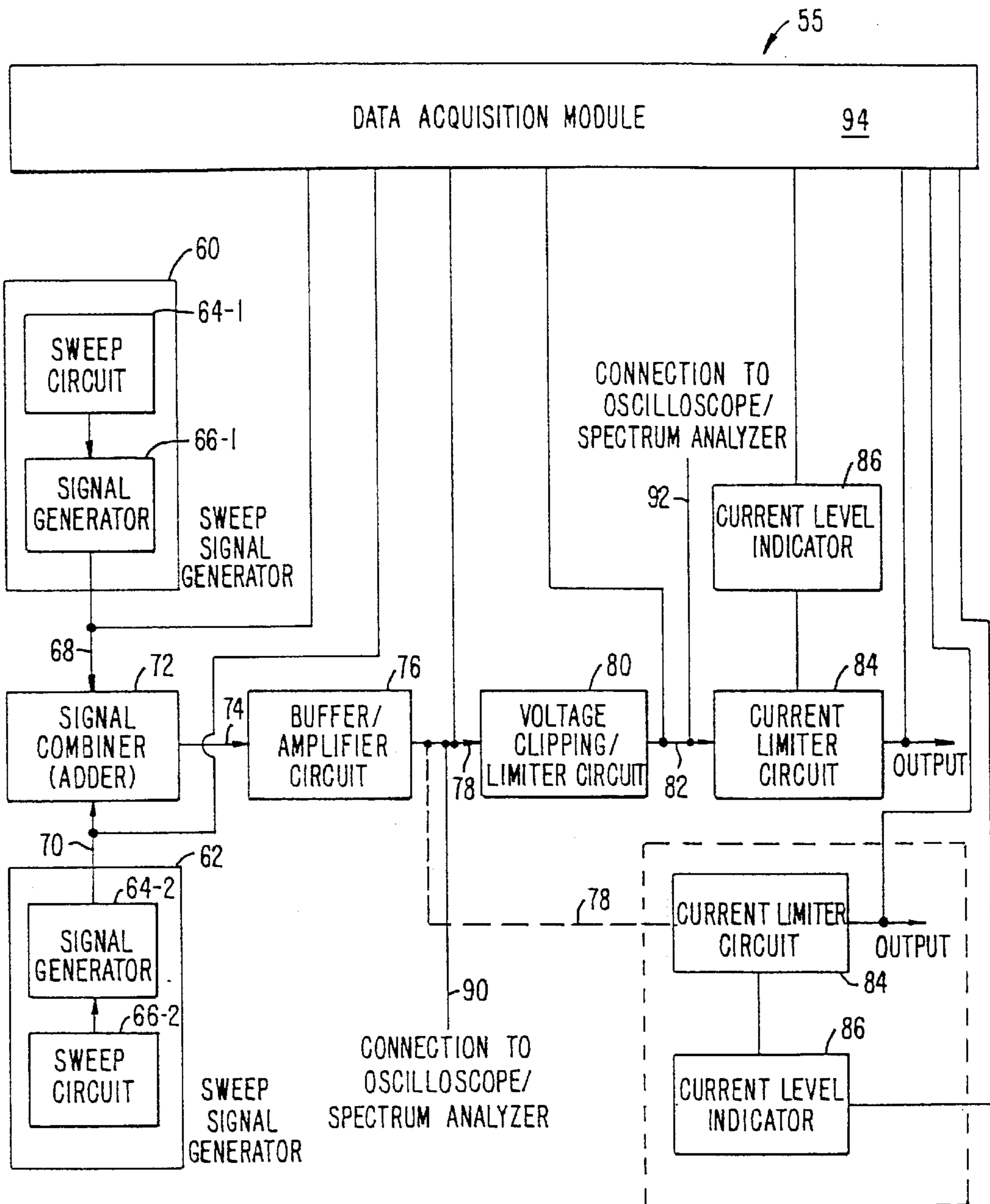


FIG. 2.

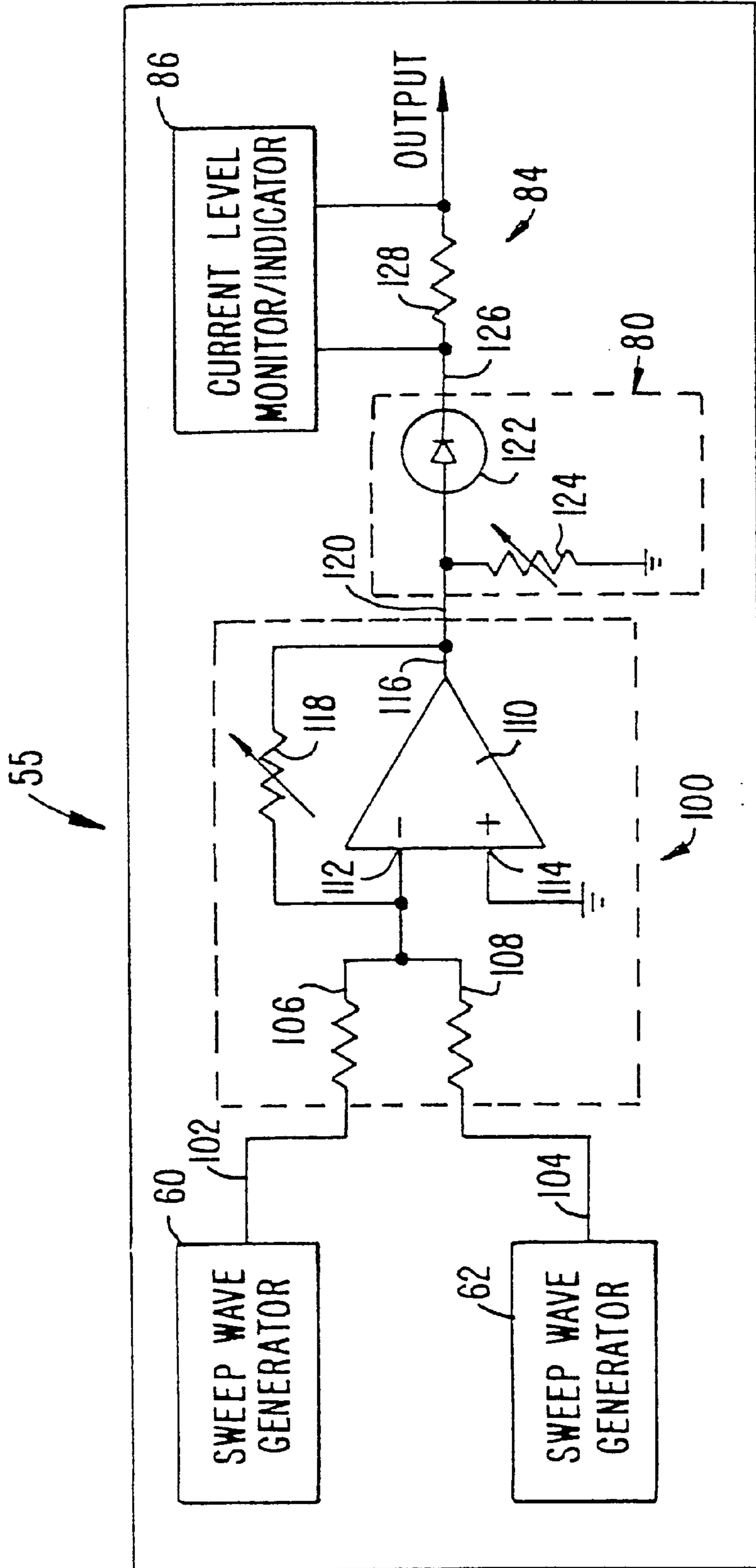


FIG. 3.

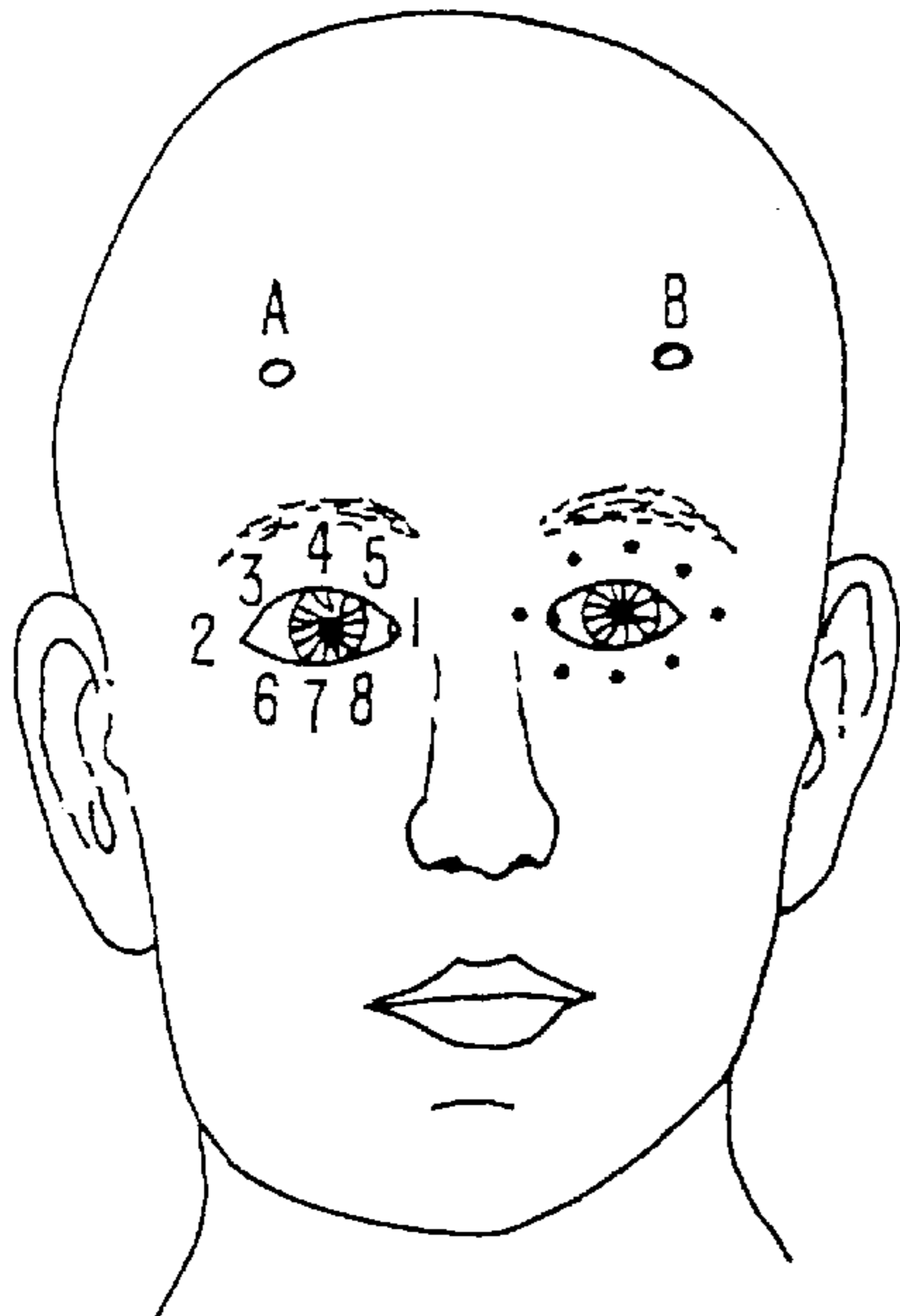


FIG. 4A.

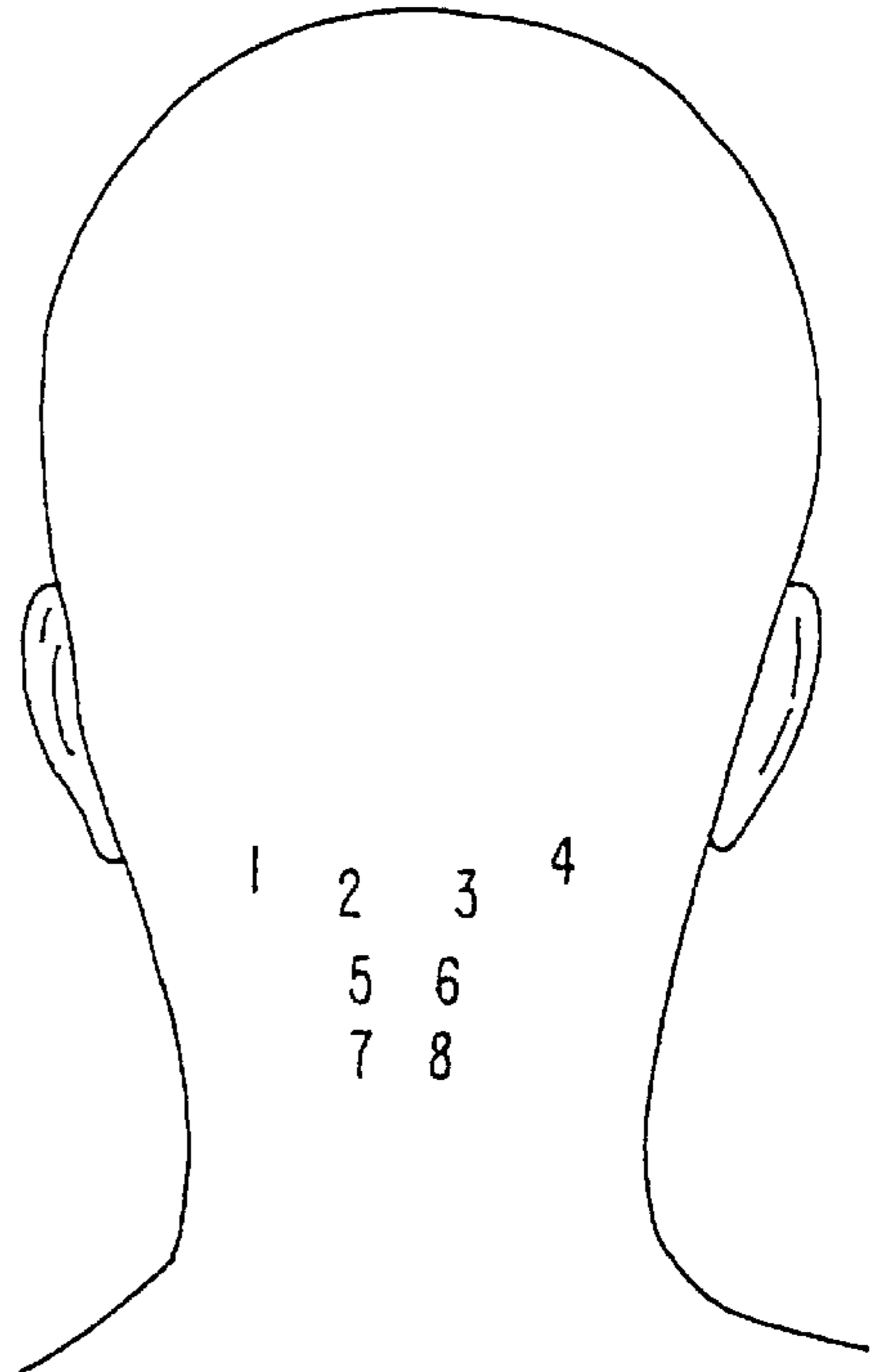


FIG. 4B.

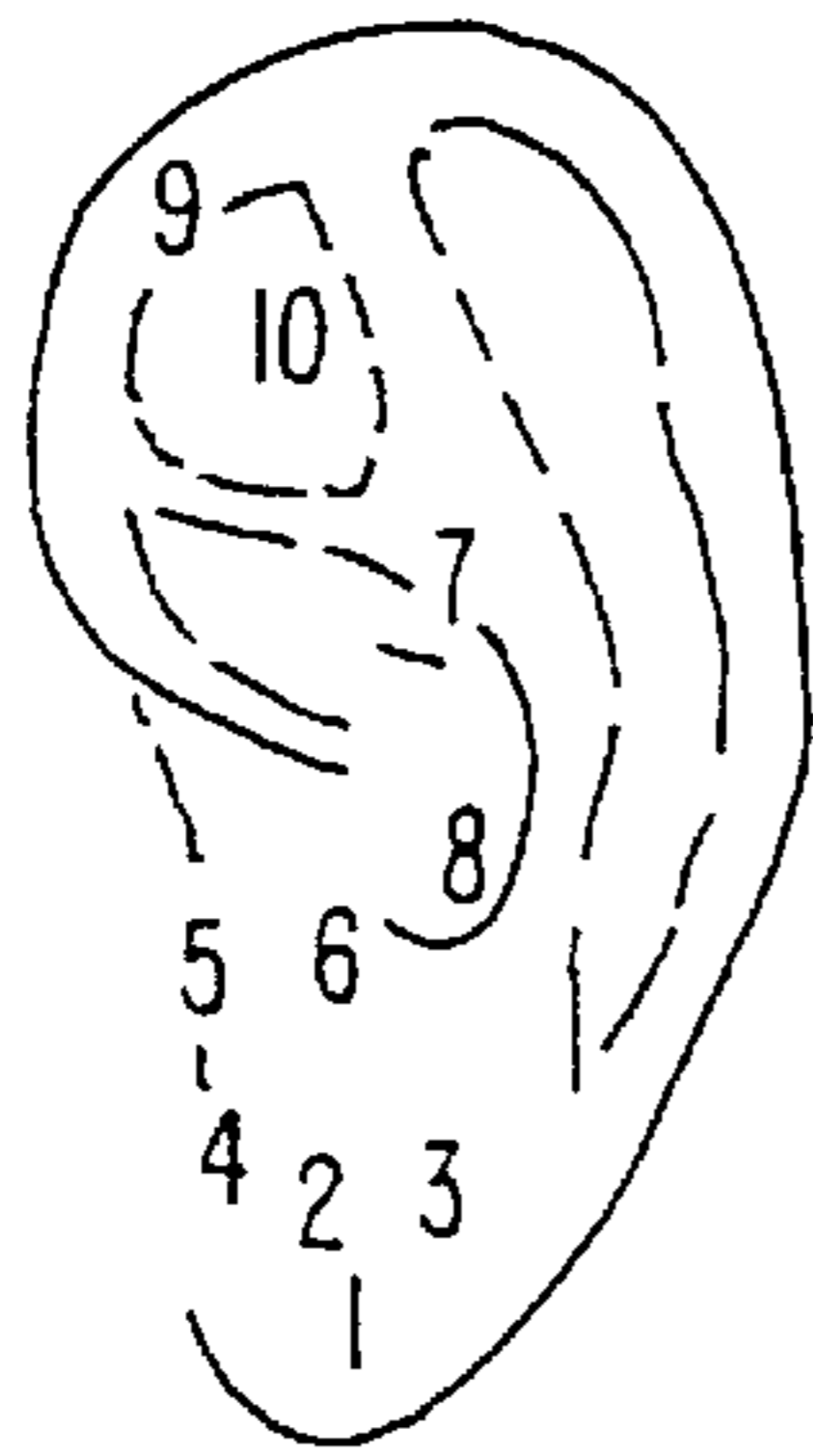


FIG. 4C.

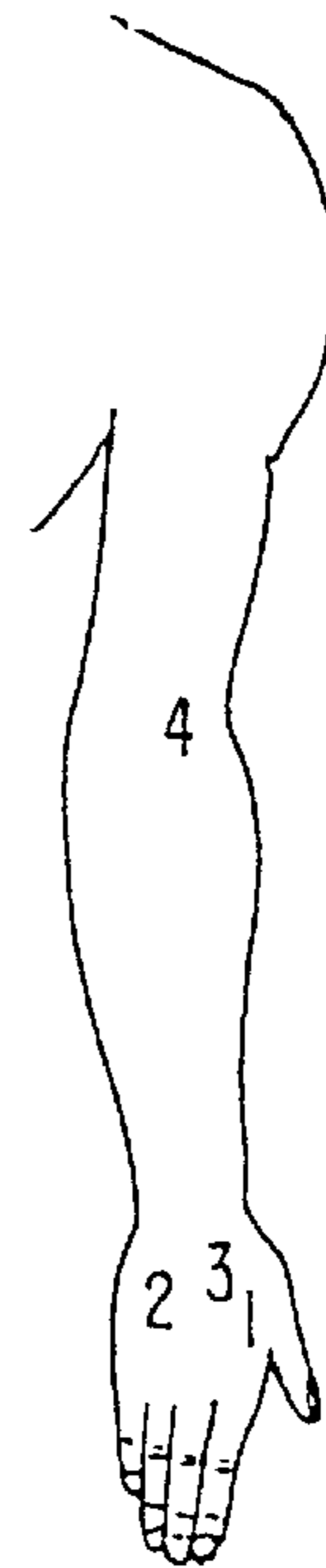


FIG. 4D.

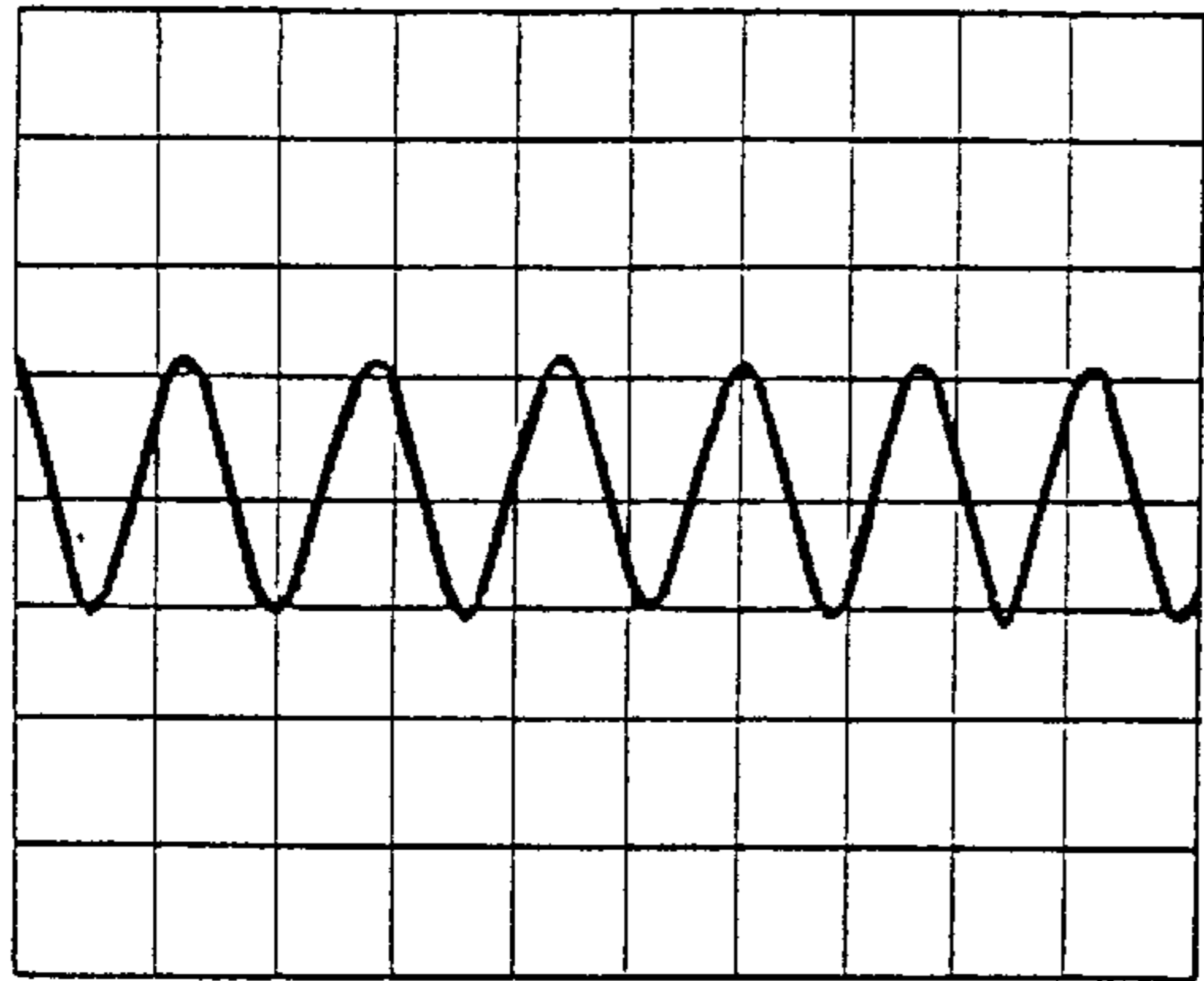


FIG. 5A.
(PRIOR ART)

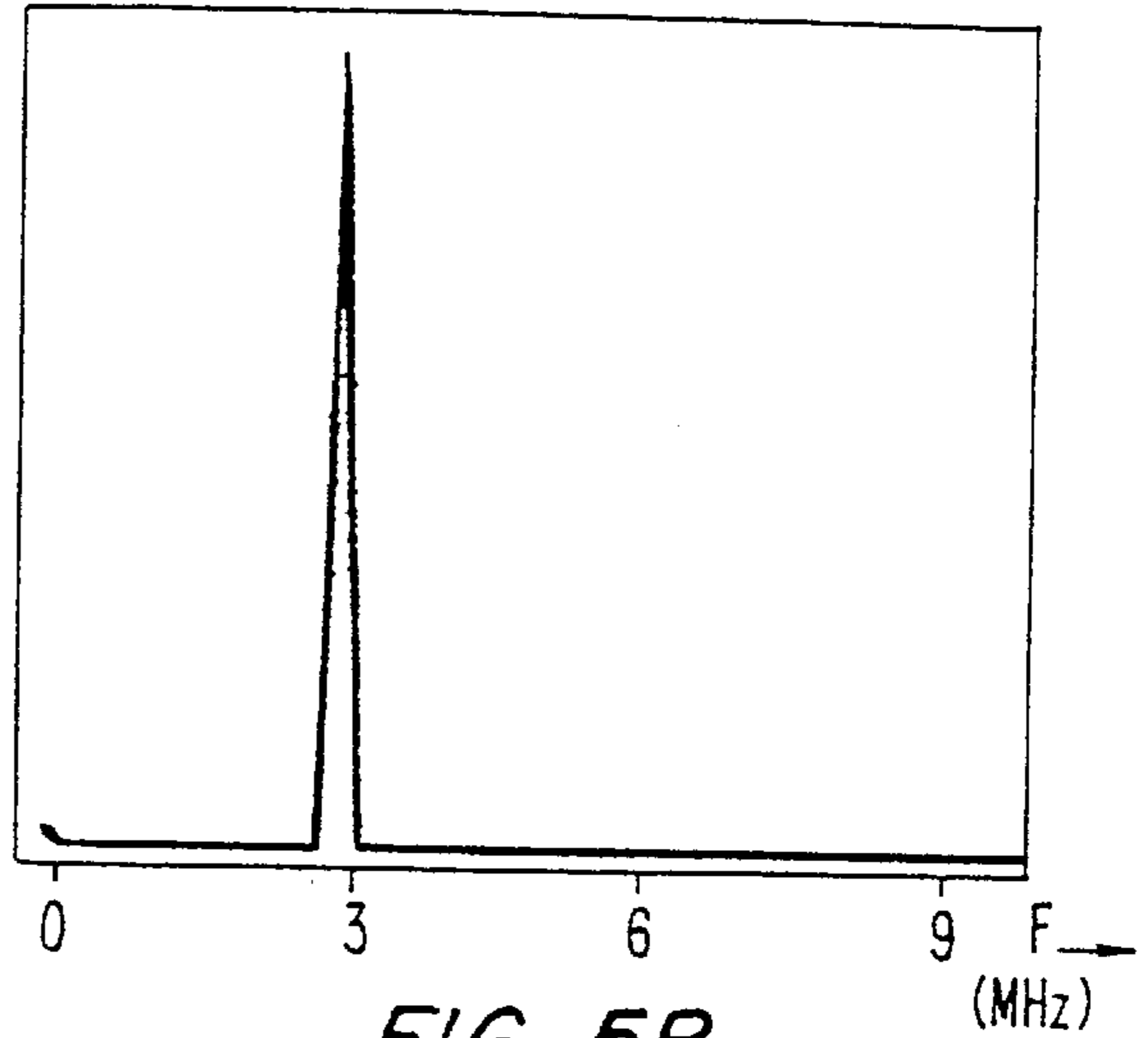


FIG. 5B.
(PRIOR ART)

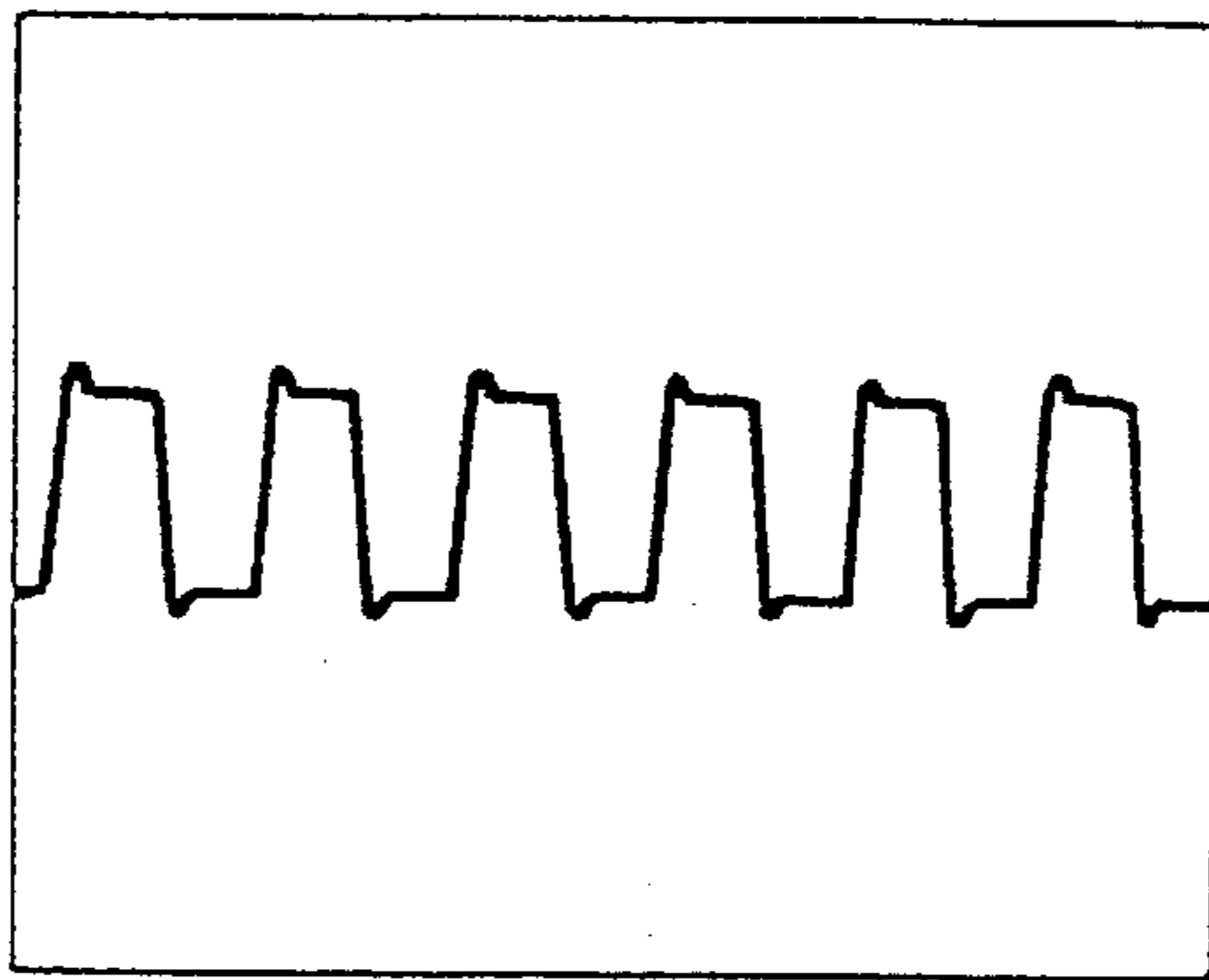


FIG. 6A. (PRIOR ART)

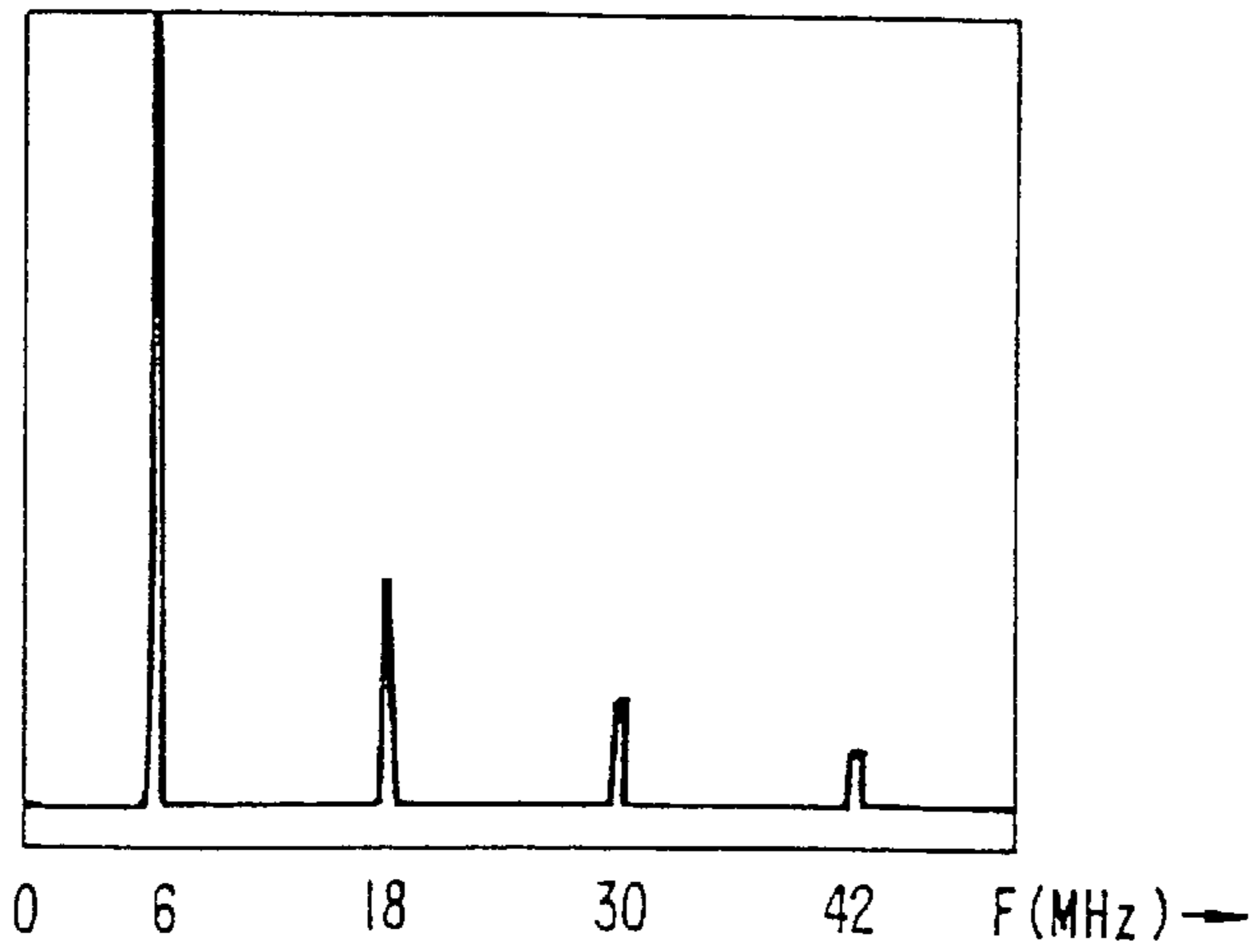


FIG. 6B. (PRIOR ART)

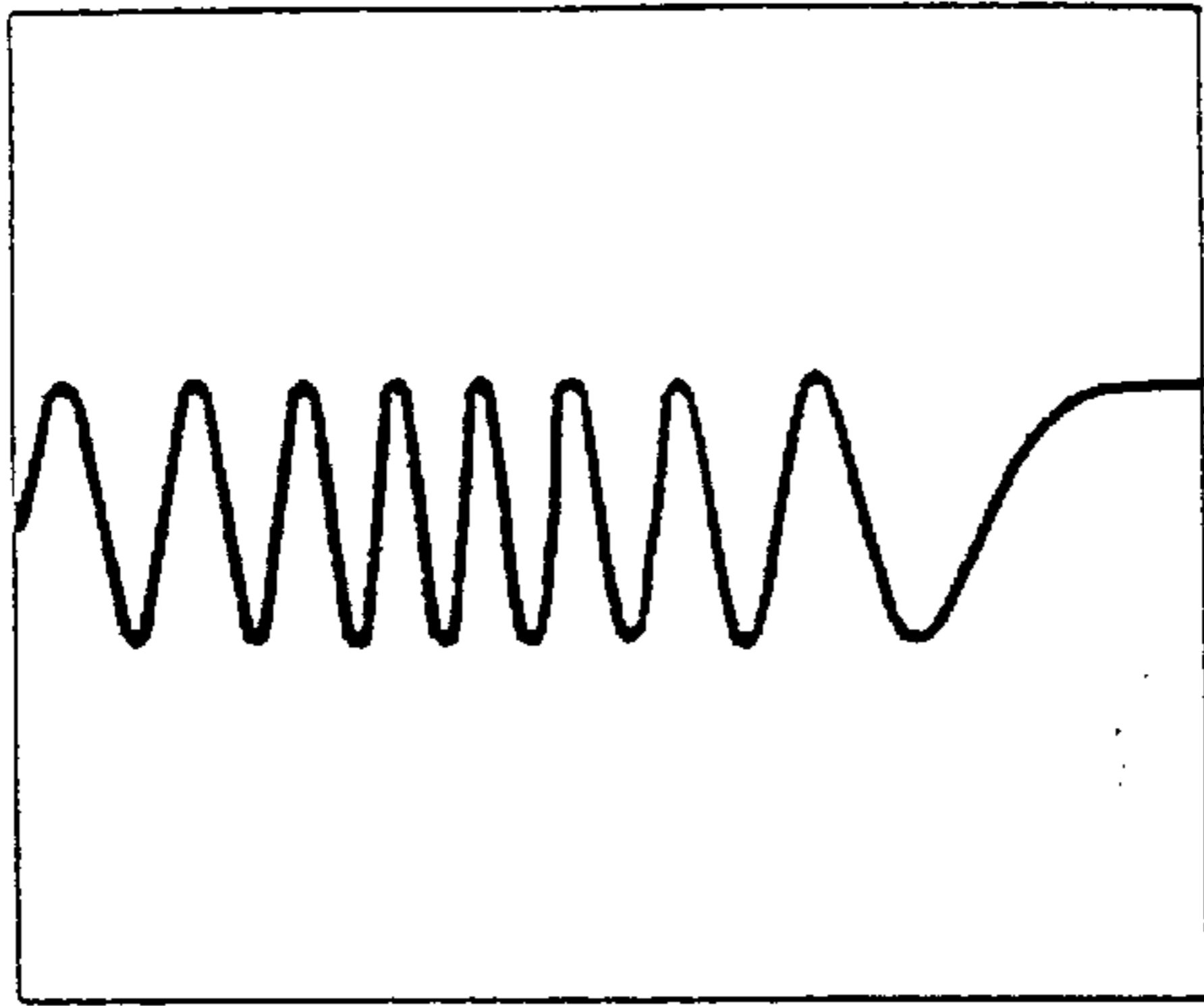


FIG. 7A.

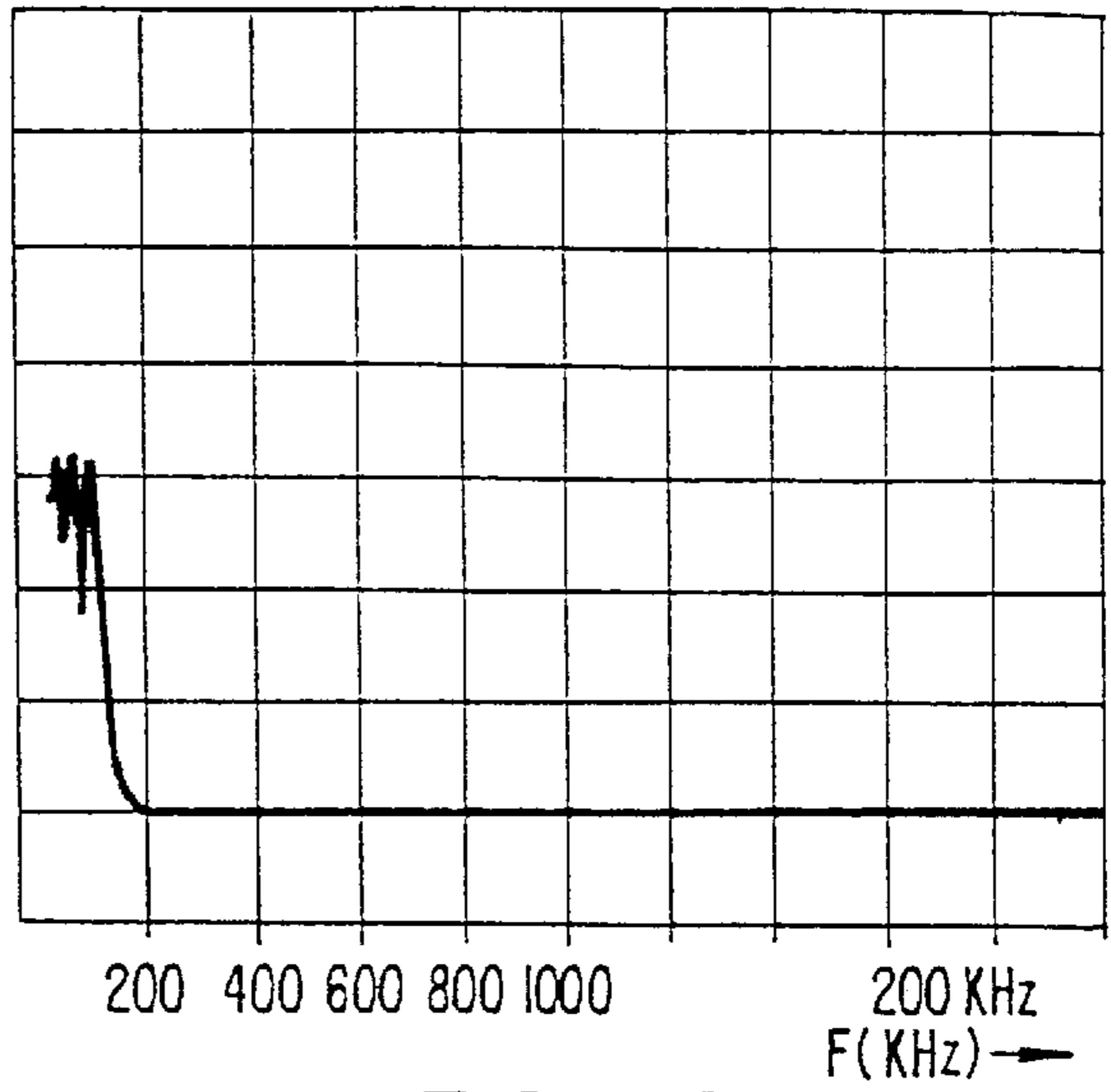


FIG. 7B.

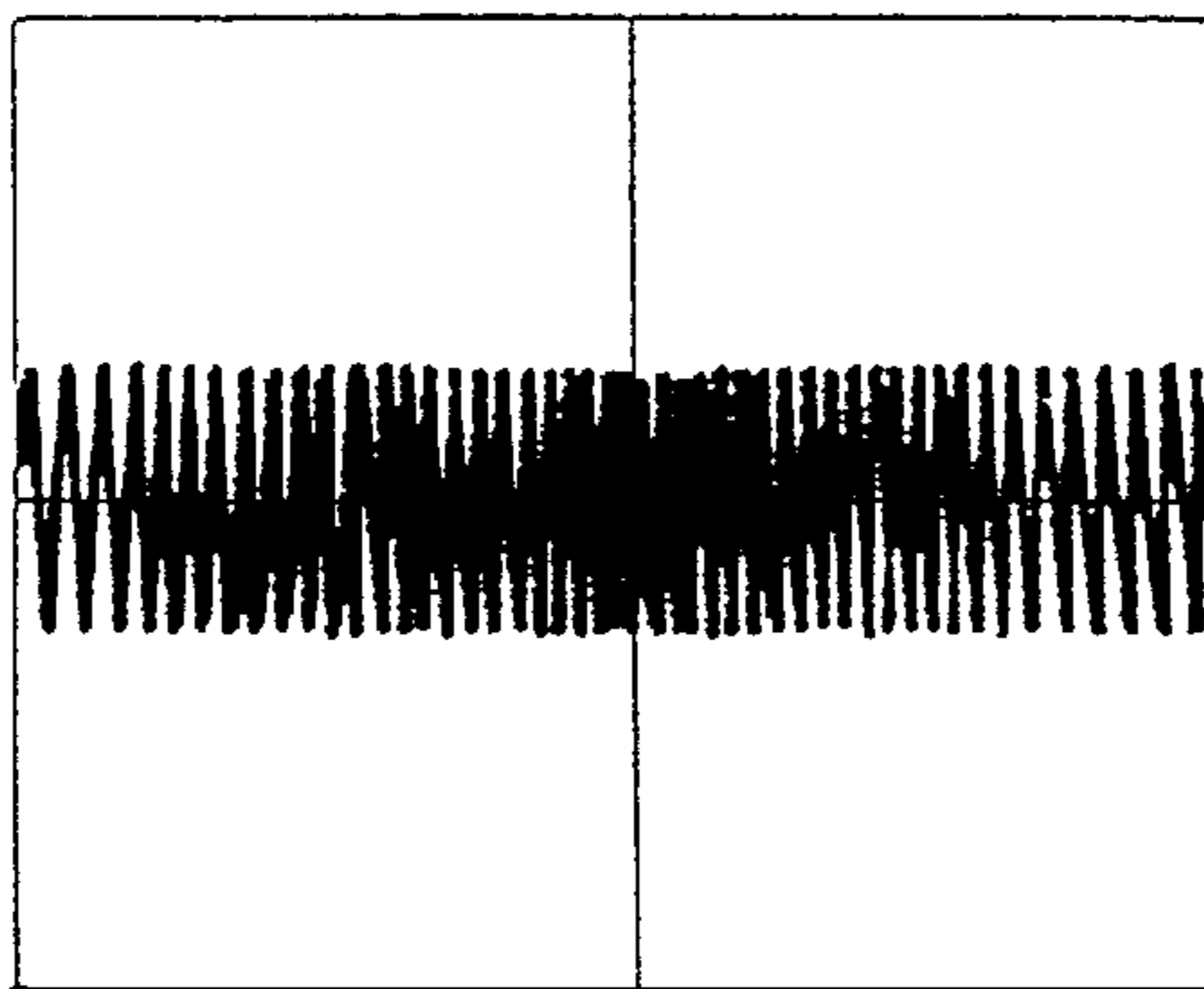


FIG. 8A.

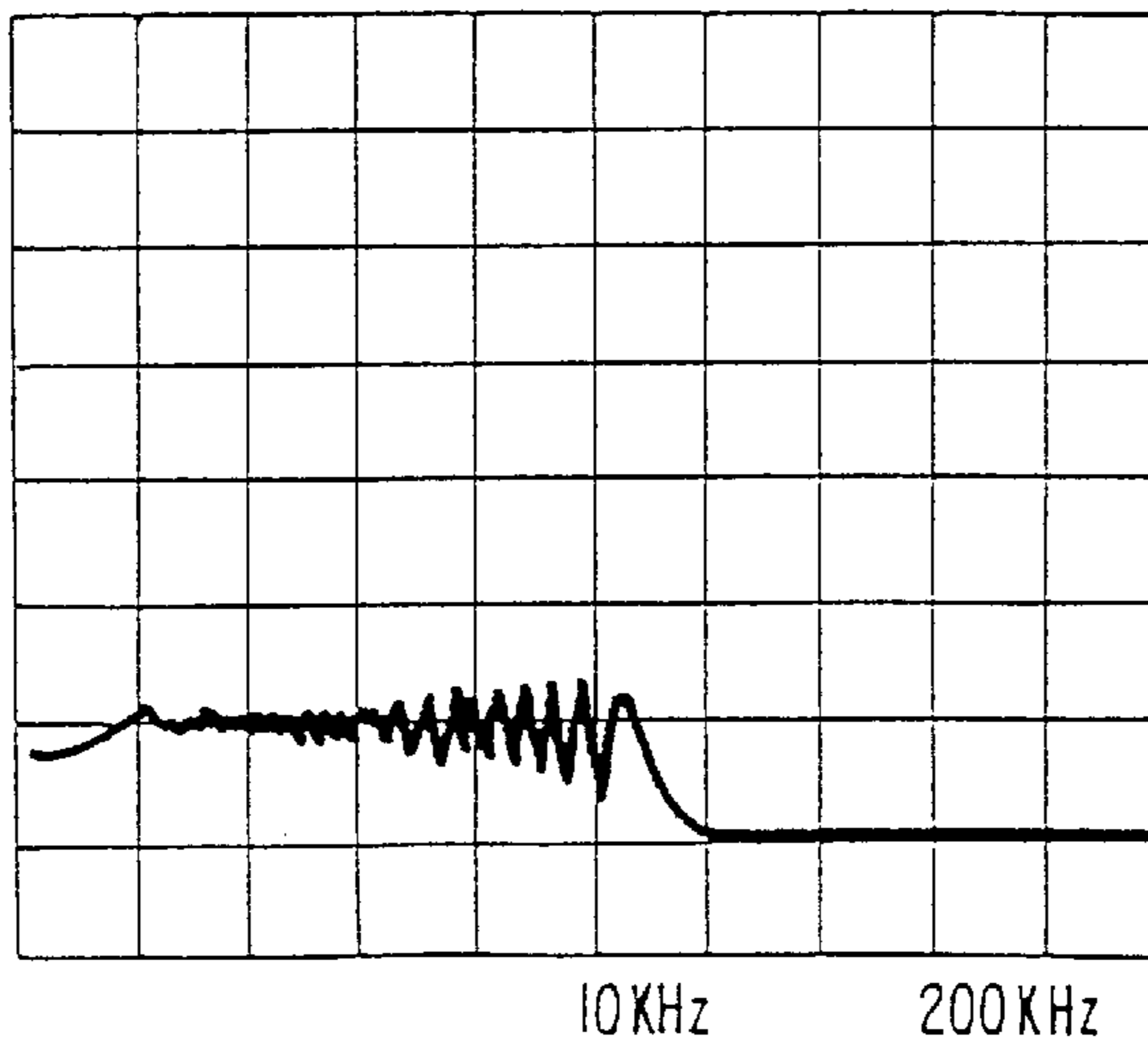


FIG. 8B.

METHODS AND APPARATUS FOR ELECTRICAL MICROCURRENT STIMULATION THERAPY

BACKGROUND OF THE INVENTION

The present invention relates generally to methods and apparatus for electrical microcurrent stimulation therapy, and more particularly to methods and apparatus for providing electrical microcurrent stimulation around an eye to combat visual system diseases, such as macular degeneration.

Chronic pain is a problem for millions of individuals throughout the world. One method of treating such pain is to provide microcurrent stimulation around or near the areas where the pain is occurring. Microcurrent, which typically is defined as current below 1 milliamp, can provide rapid and long-lasting pain relief for a wide variety of pain syndromes. Generally, microcurrent stimulation therapy typically comprises applying a current in the range of about 20 to about 300 microamps to the affected area. The current or microcurrent blocks neuronal transmission of pain signals and stimulates the release of endorphins to help relieve the pain in chronic and acute pain patients.

While the current level can be an important factor in microcurrent stimulation therapy, frequency modulation and the wave form of the electrical signal are also important. Some electrical stimulation therapy devices currently known in the art typically allow the user to manually adjust the frequency ranges and types of wave form signals applied to the patient. For example, the MicroStim 400 device, manufactured by MicroStim, Inc., located in Tamarac, Fla., features a combination of a carrier wave form having a modulated frequency thereon. The MicroStim device is covered by U.S. Pat. No. 4,989,605, issued on Feb. 5, 1991 to Joel Rossen and entitled "Transcutaneous Electrical Nerve Stimulation (TENS) Device", the contents of which is incorporated herein by reference. The theory behind the MicroStim 400 device is that the carrier wave is designed to take the modulated frequency deep into the body for consistent and rapid pain relief. However, a disadvantage of the MicroStim 400 device is that the signal that it generates produces most of its power at individual frequency 105 when viewing the spectral components of the wave signal. That is, when viewing the signal produced by the MicroStim 400 in the frequency domain, the majority of the power output from the signal resides at discrete frequencies. Accordingly, the therapeutic effect of the signal may not be maximized.

Another device which can be used for microcurrent stimulation therapy is the Amrex Z-Stim device manufactured by Amrex, Corp. of Carson, Calif. The Z-Stim device is a multi-signal interferential stimulator that provides multiple swept frequency sinusoidal signals. The applications for sinusoidal signals are more appropriate for muscle stimulation and addressing problems associated with pain, edema and rehabilitation for certain neuromuscular and orthopaedic problems.

In addition to chronic pain relief, microcurrent therapy is being used to treat a number of visual system diseases, including macular degeneration and retinitis pigmentosa.

Age-related macular degeneration (AMD) is the leading cause of legal blindness in the United States in persons over 65 years old. According to a March 1997 Review of Optometry Journal, 10% of our population over age 52 has AMD and 33% of individuals over age 75 have AMD. It is estimated that more than 13 million Americans now have

AMD and that, by the time the Baby Boomers reach age 65, there will be over 30 million cases of AMD, almost 25% of our population over 65.

Normal retinal cell function is a photochemical reaction converting light energy to an electrical impulse which travels to the brain and vision occurs. With AMD and other visual system diseases, diseased, inflamed retinal cells eventually lose cell function. Adenosine triphosphate (ATP) levels drop, protein synthesis drops, the electrical resistance goes up, and cell electricity potential goes down. Basically, the cells seem to go dormant for a time before they die. It is believed that, if electrical stimulation is provided to the cells before they die, blood vessel permeability is increased, a more normal cellular electrical potential will be achieved, the ATP levels will increase, protein synthesis will occur again, and normal cell metabolism will be restored. In addition, electrical stimulation appears to have a healing effect on the small blood vessels in the retina, promoting a more efficient delivery of nutrients to the retinal cells and a more efficient uptake of proteins that can accumulate on the retina. Thus, it is believed that microcurrent stimulation will help rejuvenate the cells in the retina to slow or stop degeneration of the eye due to AMD. With the proper microcurrent stimulation wave form and therapy procedures, AMD may be slowed or stopped in a large number of people suffering from the disease.

While microcurrent stimulation therapy has been used to treat AMD and other visual system diseases, the methods and apparatus used in the prior art do not appear to maximize the therapeutic effect. For example, as mentioned briefly above, the devices for providing microcurrent stimulation therapy are limited in the types of wave forms and frequency ranges which they may provide for therapy.

SUMMARY OF THE INVENTION

Accordingly, it is an advantage of the present invention to provide novel methods and apparatus for providing microcurrent stimulation therapy to a body part to combat chronic pain, injury, or disease in that body part.

Another advantage of the present invention is to provide methods and apparatus for treating visual system diseases, including macular degeneration and retinitis pigmentosa.

Yet another advantage of the present invention is to provide an apparatus which generates unique wave forms that can be used for microcurrent stimulation therapy.

Yet another advantage of the present invention is to provide an apparatus which can monitor the current (both RMS and average) supplied to a body part.

Still another advantage of the present invention is to provide an apparatus that has the capability to display the waveform signal in the time domain and the frequency spectrum of the signal supplied to the body part.

The above and other advantages of the present invention are carried out in one form by an apparatus for supplying an electrical signal to a body part in order to provide microcurrent stimulation therapy to the body part. The apparatus preferably comprises a first sweep wave or sweep frequency signal generator configured to generate a first sweep wave signal, a buffer amplifier circuit configured to receive the first sweep wave signal from the first sweep wave signal generator and amplify and buffer the first sweep wave signal creating a buffered sweep wave signal. In addition, the apparatus preferably includes a current limiting circuit configured to receive the buffered sweep wave signal from the buffer amplifier circuit and limit the amount of current supplied to the body part. Finally, the apparatus preferably comprises a probe for applying the sweep wave signal to the body part.

In accordance with another embodiment of the present invention, the apparatus further comprises a second sweep wave or sweep frequency signal generator configured to generate a second sweep wave signal, and a signal combining circuit configured to receive the first and second sweep wave signals from the first and second sweep wave signal generators and combine the first and second sweep wave signals into a composite sweep wave signal.

In accordance with one preferred embodiment of the present invention, the signal combining circuit and the buffer amplifier circuit of the apparatus are configured into a single circuit comprising an operational amplifier having a positive input terminal, a negative input terminal, and an output terminal. In accordance with this aspect of the invention, the positive input terminal preferably is connected to ground, the first sweep wave signal is connected to the negative input terminal through a first resistor, the second sweep wave signal is connected to the negative input terminal through a second resistor, and the output terminal of the operational amplifier is connected to the negative input terminal in a negative feedback loop through a variable resistor.

In accordance with yet another embodiment of the present invention, the microcurrent stimulation therapy apparatus further comprises a voltage limiting circuit preferably connected between the buffer amplifier circuit and the current limiting circuit for limiting or clipping the voltage wave signal output.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the present invention may be derived by referring to the detailed description and claims when considered in connection with the figures, wherein like reference numbers refer to similar items throughout the figures, and:

FIG. 1 is a diagram of a microcurrent stimulation therapy apparatus having a microcurrent signal generator and a probe for applying the microcurrent to a body part;

FIG. 2 is a block diagram of a circuit embodying the microcurrent signal generator of FIG. 1;

FIG. 3 is a detailed circuit diagram of one embodiment of the microcurrent signal generator circuit of FIG. 2;

FIG. 4a illustrates eight therapy points around an eyelid to which microcurrent stimulation therapy may be applied in accordance with a method for treating visual system diseases;

FIG. 4b illustrates eight therapy points on the back of the neck to which microcurrent stimulation therapy may be applied in accordance with a method for treating visual system diseases;

FIG. 4c illustrates ten therapy points on the ear to which microcurrent stimulation therapy may be applied in accordance with a method for treating visual system diseases;

FIG. 4d illustrates four therapy points on an arm to which microcurrent stimulation therapy may be applied in accordance with a method for treating visual system diseases;

FIG. 5a illustrates a periodic sinusoidal wave signal having a set frequency which is a wave form signal generated by a prior art microcurrent generator;

FIG. 5b illustrates the spectral or frequency response of the sinusoidal wave signal of FIG. 5a;

FIG. 6a illustrates a periodic square wave having a set frequency which is a wave form signal generated by a prior art microcurrent generator;

FIG. 6b illustrates the spectral or frequency response of the square wave signal of FIG. 6a;

FIG. 7a is a swept sinusoidal wave form signal varying from about 0 Hz to about 125 Hz over a time frame in excess of 100 microseconds;

FIG. 7b is the spectral or frequency response of the wave form signal of FIG. 7a;

FIG. 8a is a swept sinusoidal wave form varying from about 0 Hz to about 1.1 MHz over a time frame in excess of 1 microseconds; and

FIG. 8b is the spectral or frequency response of the wave form signal of FIG. 8a.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention comprises methods and apparatus for providing microcurrent simulation therapy for the treatment of chronic pain and other bodily defects or diseases. More particularly, the present invention relates to a microcurrent wave form generator which generates sweep wave signals for use in microcurrent stimulation therapy. As discussed in more detail below, the microcurrent sweep wave generator disclosed herein may be used for any type of microcurrent stimulation therapy and will find its greatest use in treating patients suffering from macular degeneration.

In addition, the present invention relates to a novel method for treating visual system diseases such as macular degeneration and retinitis pigmentosa using microcurrent stimulation therapy techniques.

With reference to FIG. 1, a novel microcurrent stimulation therapy apparatus 10 is shown in accordance with the present invention. Therapy apparatus 10 preferably comprises a sweep wave signal generator 12, a stimulation probe 14, and an electrode 16. Preferably, stimulation probe 14 is connected to sweep wave signal generator 12 via a first electrical connector 18, and electrode 16 is connected to sweep wave signal generator 12 via a second electrical connector 20. As illustrated in FIG. 1, a probe tip 22 preferably is connected to the end of stimulation probe 14 opposite the end of probe 14 connected to first electrical connector 18.

Stimulation probe 14 preferably comprises a shielded hand-held probe configured to administer microcurrent stimulation to various points on one or more body parts. In accordance with a preferred embodiment of the present invention, probe tip 22 preferably comprises a cotton swab moistened or dampened with a conductive gel. The dampened cotton swab allows for the gentle administration of the microcurrent to the body part without undue discomfort. However, while one embodiment of the present invention illustrates a probe tip 22 as being a cotton swab, one skilled in the art will appreciate that other types of probe tips may be used. For example, probe tip 22 may be made from a variety of different metals like copper, brass, aluminum, or the like, or probe tip 22 may be made from metal combinations or other conductive materials. In any event, any suitable probe tip may be used and, thus, the present invention is not limited to the illustrated embodiment.

In accordance with a preferred embodiment of the present invention, electrode 16 preferably comprises a handheld brass electrode. As one skilled in the art will appreciate, when a patient receiving microcurrent stimulation therapy holds electrode 16, a closed circuit is created with stimulation probe 18. That is, by holding electrode 16, current from probe 18 will travel through the body, to brass electrode 16 and back to sweep wave signal generator 12.

While the illustrated embodiment shows a handheld brass electrode 16, any electrode configuration may be used. For

example, electrode 16 may be a conductive clip device which attaches to a body part such as a finger, ear, arm or the like.

As discussed briefly above, first electrical connector 18 is configured to connect stimulation probe 14 to sweep wave signal generator 12, and second electrical connector 20 is configured to connect electrode 16 to sweep wave signal generator 12. In the illustrated embodiment, first and second electrical connectors 18 and 20 each preferably include a first connector end 24 for connection to generator 12 and a second connector end 26 for connection to stimulation probe 14 and electrode 16, respectively. In accordance with this aspect of the invention, connectors 18 and 20 are removable from generator 12 and probe 14 and electrode 16.

In accordance with an alternative embodiment of the present invention, connectors 18 and 20 may be hardwired to generator 12, or to probe 14 and electrode 16, or to both generator 12 and probe 14 and electrode 16. In addition, in accordance with yet another alternative embodiment of the present invention, electrical connectors 18 and 20 may comprise any suitable electrical connection device currently known in the art or hereinafter developed.

Still referring to FIG. 1, a more detailed description of sweep wave signal generator 12 will now be discussed. As discussed in detail below, sweep wave signal generator 12 preferably is configured to generate one or more sweep wave signals having various wave form, sweep frequency, sweep time, duty cycle, center frequency, frequency window, and amplitude characteristics. In accordance with a preferred embodiment of the invention, the generated sweep wave signal(s) are frequency varied signals. That is, the frequency of the signals vary over time.

To generate the different sweep wave signals, sweep wave signal generator 12 may produce a single sweep wave signal, or alternatively, sweep wave signal generator 12 may generate a composite signal comprising two independent swept wave signals or a swept wave signal and a non-swept wave signal. In accordance with this aspect of the present invention, sweep wave signal generator 12 preferably comprises a first wave form control 32 and a second wave form control 34. First wave form control 32 preferably controls the wave form type of a first sweep wave signal, and second wave form control 34 preferably controls the wave form type of a second sweep wave signal. First and second wave form controls 32 and 34 may be adjusted to produce a variety of different sweep wave forms. For example, by adjusting first and second controls 32 and 34, generator 12 will produce different wave forms, including sinusoidal wave forms, ramp wave forms, triangular wave forms, rectangular or square wave forms, step wave forms, window wave forms, unipolar wave forms, bipolar or biphasic wave forms or steady-state DC signals, to name a few. By combining different wave form types having different sweep frequencies and sweep times, a large variety of therapeutic sweep waves may be generated.

In addition to controlling the type of wave forms generated, sweep wave signal generator 12 preferably is configured to control the range of frequencies between which the selected wave forms sweep, as well as the sweep time for performing the sweep of frequency ranges. In accordance with this aspect of the invention, generator 12 preferably has a first low frequency control 36, a first high frequency control 38, a first sweep time control 39, a second low frequency control 40, a second high frequency control 42, and a second sweep time control 43. First low frequency control 36 preferably controls the low frequency threshold

for the first sweep wave signal, first high frequency control 38 controls the high frequency threshold of the first sweep wave signal, and first sweep time control 39 controls the sweep time of the first sweep wave signal. Similarly, second low frequency control 40 preferably controls the low frequency threshold of the second sweep wave signal, second high frequency control 42 controls the high frequency threshold of the second sweep wave signal, and second sweep time control 43 controls the sweep time of the second sweep wave signal.

In accordance with a preferred embodiment of the present invention, the low frequency thresholds for both sweep wave signals may be in the range of about 0 Hz to about 400 Hz. Similarly, the high frequency threshold for the two sweep wave signals may be in the range of about 0 Hz to about 2000 Hz. The sweep time for both the first and the second sweep wave signals preferably is in the range of about 7 seconds to about 60 seconds, and more preferably about 15 seconds. While the illustrated embodiment shows a low frequency control and a high frequency control for each sweep wave signal, one skilled in the art will appreciate that any frequency control scheme may be used. For example, each sweep wave signal may have only one frequency control, or one low and one high frequency control may control both sweep wave signals. In any event, the present invention is not limited to the illustrated embodiment.

Still referring to FIG. 1, sweep wave signal generator 12 preferably further comprises a voltage signal control 44, a current control 46, a first signal monitor port 50, a second signal monitor port 52, and a data-acquisition system port 54.

As discussed in more detail below with reference to FIGS. 2 and 3, sweep wave signal generator 12 preferably further comprises a voltage limiting circuit and a current limiting circuit. In accordance with this aspect of the invention, voltage control 44 is configured to control the magnitude of the voltage signal peak or peak-to-peak output. Similarly, current control 46 preferably is configured to control the current supplied to the body part of the patient by controlling the current limiting circuit.

As discussed in greater detail below, sweep wave signal generator 12 may be connected to one or more oscilloscopes, spectrum analyzers or wave form displays via first and second signal monitor ports 50 and 52. By connecting generator 12 to one or more oscilloscopes, spectrum analyzers, or wave form displays, the wave form signal and current level at various locations within the generator circuit can be monitored. In addition, sweep wave signal generator 12 may further include a data-acquisition port 54 for connecting generator 12 to a data-acquisition system and/or a strip chart recorder. In accordance with this aspect of the present invention, generator 12 preferably is configured to record various data, such as wave form, current and voltage levels, and the like for different patients, and then download the data to a data-acquisition system for monitoring and analysis. In this manner, a doctor or practitioner can analyze data concerning variations in current levels between patients and different diseases of the visual system, as well as variations in the swept wave form for different patients and disease states. The doctor or practitioner can then use this data to track therapy progress, develop better therapy procedures for different patients, and monitor variabilities in treatment points. In addition, the doctor or practitioner can monitor probe contact consistency and patient progress for self-administered therapy patients. That is, for patients who use or administer the micro-current stimulation therapy to

themselves, at home, the doctor or practitioner can use the collected data to determine whether the patient is administering the therapy correctly and whether the therapy protocol needs to be adjusted for that particular patient.

As one skilled in the art will appreciate, sweep wave signal generator **12** may include both voltage control **44** **30** and current control **46**, or generator **12** may be configured with only one of the two controls. For example, by controlling the magnitude of the voltage output signal for a give patient impedance, the current supplied to the patient is also controlled. Similarly, by controlling the current supplied to a patient having a given impedance, the voltage is also controlled. Thus, the present invention is not limited to the illustrated embodiment. In addition, while the illustrated embodiment of sweep wave signal generator **12** shows a number of different control features, one skilled in the art will appreciate that certain control features may be eliminated and other control features may be added without departing from the spirit of the invention. For example, while not illustrated in the figures, sweep wave signal generator **12** may further comprise duty cycle controls for controlling the duty cycles of the first and second sweep wave signals.

Finally, sweep wave signal generator **12** preferably further comprises a current level indicator **48**, a first frequency indicator **49-1**, and a second frequency indicator **49-2**. In accordance with this aspect of the invention, current level indicator **48** preferably displays the current being supplied to the patient. Current level indicator **48** may be configured to display root-mean-square (rms) or average current output.

In addition, in accordance with one embodiment of the present invention, first and second frequency indicators **49-1** and **49-2** preferably are configured to display the frequency of the first and second sweep wave signals, respectively, as the signal sweeps through the frequency ranges. Alternatively, in accordance with another embodiment of the present invention, first and second frequency indicators **49-1** and **49-2** may be configured to display the frequency ranges between which the first and second sweep waves are to sweep.

Referring now to FIG. 2, a block circuit diagram of one embodiment of a sweep wave signal generator circuit **55** is illustrated. In accordance with a preferred embodiment of the present invention, sweep wave signal generator circuit **55** preferably comprises a first sweep signal generator **60**, and a second sweep signal generator **62**. Both first and second sweep wave signal generators **60**, **62** preferably comprise a sweep control circuit **64** and a signal generator **66**. Sweep control circuit **64** preferably controls the sweep frequencies, sweep times and duty cycles of the signals, and signal generator **66** preferably generates a particular wave form having the sweep frequencies, sweep times and duty cycles dictated by control circuit **64**. First and second sweep wave signal generators **60** and **62** may be configured to generate swept waves, or non-swept waves. For example, by setting the high and low sweep frequencies to the same frequency for a particular signal, the signal generator will generate a signal having a set frequency.

As one skilled in the art will appreciate, first and second sweep signal generators **60** and **62** may comprise any suitable sweep signal generator currently known in the art. For example, function generator with sweep control, product no. PM5132, manufactured by Philips Corporation, may be used. As discussed briefly above, sweep signal generator **60** and **62** may be configured to generate a wide variety of wave forms having a variable range of sweep frequencies and sweep times.

In accordance with the embodiment illustrated in FIG. 2, first sweep signal generator **60** preferably generates a first sweep wave signal **68** and second sweep signal generator **62** preferably generates a second sweep wave signal **70**. A signal combiner/adder circuit **72** preferably receives first sweep wave signal **68** and second sweep wave signal **70** and combines the two signals into a single sweep wave signal **74**. From combiner/adder circuit **72**, sweep wave signal **74** preferably passes to a buffer/amplifier circuit **76**, which is configured to amplify and buffer single sweep wave **74**, generating a buffered sweep wave signal **78**.

In accordance with one embodiment of the present invention, buffered sweep wave signal **78** preferably passes into a voltage clipping or limiting circuit **80**, which is configured to control the polarity of the output voltage to a predetermined voltage level and polarity. The output of clipping or limiting circuit **80** is a clipped voltage signal **82** which preferably passes to a current limiting circuit **84** configured to limit the total current output supplied to a particular body part. Connected to current limiting circuit **84** is a current level indicator **86**, which preferably is a volt meter configured to monitor and display the output current level.

As mentioned briefly above, sweep wave signal generator **12** preferably comprises a voltage control **44** and a current control **46**. In accordance with this aspect of the invention, voltage control **44** preferably is configured to control the voltage signal peak or peak-to-peak output from voltage clipping or limiting circuit **80**. For example, by adjusting voltage signal control **44**, voltage clipping or limiting circuit **80** is adjusted so that the amplitude of the output voltage changes as necessary. Similarly, current control **46** of signal generator **12** preferably is configured to control the current output from current limiting circuit **84**.

Current level indicator **86** may comprise any suitable current measuring and displaying device. As discussed in more detail below with reference to FIG. 3, current level indicator **86** may comprise, for example, a voltage measuring device configured across current limiting circuit **84**. As one skilled in the art will appreciate, the amount of current flowing through current limiting circuit **84** is a function of the voltage across the circuit, as well as the resistance of the circuit itself. Once the current level is determined, current level indicator **86** preferably displays the current level on current level display **48** of signal generator **12** (see FIG. 1). Current level indicator **86** can be configured to measure the root-mean-square (RMS) current, or indicator **86** may be configured to measure an average current over a particular time period.

In accordance with another preferred embodiment of the present invention, signal generator circuit **55** may be configured without voltage clipping or limiting circuit **80**. In accordance with this preferred embodiment of the invention, amplified sweep wave signal **78** passes directly to current limiting circuit **84**. This particular embodiment of the invention is illustrated in FIG. 2 as dotted line **78** passing into circuit **88** comprising current limiting circuit **84** and current level indicator **86**. In accordance with this second embodiment of the present invention, current limiting circuit **84** and current level indicator **86** preferably operate in the same general manner as that described above with reference to the first embodiment. Accordingly, a detailed discussion of circuit **88** will not be discussed further.

In accordance with yet another embodiment of the present invention, sweep wave signal generating circuit **55** may further comprise connections **90** and **92** for connection to

one or more oscilloscopes, spectrum analyzers or wave form displays. As illustrated in FIG. 2, in accordance with a preferred embodiment of the present invention, signal generating circuit 55 preferably has two connections, one prior to voltage clipping or limiting circuit 80 and one after voltage clipping or limiting circuit 80. In accordance with this aspect of the invention, an oscilloscope, spectrum analyzer, or wave form display connected to connection 90 will display the wave form of the sweep wave signal from buffer/amplifier circuit 76, and the second oscilloscope, spectrum analyzer, or wave form display connected to connection 92 will display the sweep wave signal after it has passed through voltage clipping or limiting circuit 80. Accordingly, the operator of the device can be sure that voltage clipping or limiting circuit is functioning properly by analyzing the signals entering and leaving the circuit. In the embodiment in which the voltage clipping or limiting circuit is eliminated, only one connection to an oscilloscope or spectrum analyzer is present.

In addition, as mentioned briefly above, the sweep wave signal generator circuit 55 may further comprise a data acquisition module 92 for collecting data about the performance of the therapy device, and in particular, generator circuit 55. For example, in accordance with the illustrated embodiment, data acquisition circuit 92 preferably is connected so that it can monitor first and second sweep waves 68 and 70, buffered sweep wave signal 78, clipped voltage signal 82, the current level from current level indicator 86, and the output signal. In accordance with this aspect of the invention, the collected data can then be downloaded to data acquisition system for analysis by a doctor or therapist. As one skilled in the art will appreciate, the data acquisition system may comprise any suitable data acquisition system, such as a computer system configured to manipulate and display such data.

Referring now to FIG. 3, a detailed circuit diagram of one embodiment of sweep wave signal generating circuit 55 is illustrated. In accordance with the illustrated embodiment in FIG. 3, signal generating circuit 55 preferably comprises a first sweep wave signal generator 60, a second sweep wave signal generator 62, a signal combiner or adder circuit 72 a buffer/amplifier circuit 76, a voltage limiting or clipping circuit 80, a current limiting circuit 84 and a current level monitor/indicator 86.

In accordance with this particular embodiment of the present invention, signal adder or combiner circuit 72 and buffer/amplifier circuit 76 preferably are combined into a single operational amplifier circuit 100. Op amp circuit 100 preferably receives a first sweep wave signal 102 from first sweep wave signal generator 60 and a second sweep wave signal 104 from second sweep wave signal generator 62. In accordance with this aspect of the invention, first sweep wave signal 102 is connected to negative input terminal 112 of an op amp 110 through a first resistor 106, and second sweep wave signal 104 is connected to negative input terminal 112 of op amp 110 through a second resistor 108. First resistor 106 and second resistor 108 preferably are in the range of about 1 kilohm to about 25 kilohms, and more preferably are about 10 kilohms.

Op amp 110 further comprises a positive input terminal 114 which preferably is connected to ground, and an output terminal 116 which preferably is connected in a negative feedback loop to negative input terminal 112 through a variable resistor 118. In accordance with a preferred embodiment of the present invention, variable resistor 118 may have a variable resistance which ranges between about 1 to about 50 kilohms, and more preferably ranges between about 3.3 to about 7.8 kilohms.

While one embodiment of the present invention disclosed herein utilizes an op amp as a signal adder and buffer amplifier, one skilled in the art will appreciate that other circuit configurations may be used to accomplish the amplifier, adder, and buffering tasks. Thus, the present invention is not limited to an embodiment comprising an op amp circuit.

From operational amplifier circuit 100, a single sweep wave signal 120 passes into voltage clipping or limiting circuit 80. In accordance with this aspect of the invention, voltage clipping or limiting circuit 80 preferably comprises a diode 22 and a variable resistor 124. Variable resistor 124 is connected between a first terminal of diode 122 and ground. With this particular configuration, the adjustment of variable resistor 124 preferably adjusts the limit of the voltage amplitude output. In accordance with a preferred embodiment of the invention, variable resistor 124 preferably has a resistance which ranges between about 5 to about 50 kilohms, and more preferably between about 15 to about 25 kilohms.

While the illustrated embodiment of the present invention shows voltage clipping or limiting circuit 80 comprising a resistor/diode combination, one skilled in the art will appreciate that any voltage limiting circuit configuration may be used. For example, instead of a diode/resistor combination, voltage clipping or limiting circuit 80 may comprise an operational amplifier configured as a limiting circuit. Therefore, the present invention is not limited to the illustrated embodiment.

From voltage limiting circuit 80, a clipped wave signal 126 preferably passes into current limiting circuit 84. In accordance with the illustrated embodiment of the invention, current limiting circuit 84 comprises a resistor 128. As one skilled in the art will appreciate, since current equals the voltage divided by the resistance ($I=V/R$), the higher the value of the resistor 128, the lower the current output. In accordance with the preferred embodiment of the invention, resistor 128 preferably has a value between about 10 and about 500 kilohms, and more preferably a value between about 20 kilohms and about 115 kilohms.

While the illustrated embodiment shows resistor 128 as a constant resistance value, one skilled in the art will appreciate that to have a controllable or variable current output, it may be desirable to replace constant resistor 128 with a variable resistor. In addition, while current limiting circuit 84 is shown as a resistor, any suitable current limiting circuit configuration may be used. For example, a circuit comprising transistors, resistors, diodes, and the like may be used instead of a simple resistor.

As discussed above, current level monitor/indicator 86 is configured to measure the current output from current limiting circuit 84. In the illustrated embodiment, current level monitor/indicator 86 preferably comprises a device which is configured to measure the voltage across resistor 128, which in turn will give the current flowing through the resistor. However, other current monitoring devices or circuits may be used. In addition, as discussed above with reference to FIG. 2, circuit 55 may further comprise a data acquisition module for collecting therapy and wave form data.

The fundamental difference between the swept and the non-swept wave form is the continuous nature of the spectral characteristics and the time-frequency variation with the wave form. There appears to be some evidence that the human body behaves like a dispersive filter and a wave form that is swept in the appropriate manner may be preferred for electrotherapy. Also, since the physiology and body chem-

istry for each patient varies, the swept wave form is more likely to provide the optimal frequency which maximizes the therapeutic value for large numbers of people afflicted with various types of visual system diseases.

Referring now to FIGS. 5a, 5b, 6a, 6b, 7a, 7b, 8a, and 8b, fundamental differences between discreet frequency wave signals and sweep wave signals is illustrated. Specifically, FIG. 5a illustrates a 2 volt (peak-to-peak) sinusoidal wave form having a set frequency of about 3 MHz. This type of wave form is a typical wave form generated by microcurrent stimulation devices currently known in the art. As illustrated in FIG. 5b, the spectral or frequency components of the sinusoidal wave form appear at only one discreet frequency. With this type of signal, all of the power from the signal is located at or near the 3 MHz frequency.

FIG. 6a illustrates a 3.2 volt (peak-to-peak) rectangular wave form having a peak overshoot and a frequency of about 6 MHz. Again, this wave form type is a typical wave form produced by microcurrent stimulation devices currently known in the art. As illustrated in FIG. 6b, the rectangular wave form has a fundamental frequency component at 6 MHz and diminishing harmonics at 18, 30 and 42 MHz, respectively. With this type of signal, approximately 80% of the power is associated with the fundamental frequency of 6 MHz.

Referring now to FIG. 7a, a 10 volt (peak-to-peak) swept sinusoidal wave form varying from about 0 Hz to about 125 Hz over a time frame of more than 100 microseconds is shown. As illustrated in FIG. 7a, the frequency of the wave form changes with time. FIG. 7b shows the frequency or spectral characteristics of the wave form of FIG. 7a. Specifically, as illustrated FIG. 7b, the frequency or spectral characteristics of the wave form are continuous, not discreet, like they are with the fixed frequency signals of FIGS. 5b and 6b. Thus, the power is not concentrated at one or a few frequencies, but is spread over the entire frequency range. The power at any discreet frequency in the spectrum is 0 watts.

Finally, FIG. 8a illustrates a 10 volt (peak-to-peak) swept sinusoidal wave form varying from 0 Hz to 1.1 MHz over a time frame of more than 100 microseconds is shown. Again, as shown in FIG. 8b, the frequency or spectral characteristics of the swept wave form is continuous over the wide frequency range and, thus, the power is spread out over all frequencies. As mentioned briefly above, from the standpoint of patient variability, such wave form characteristics are preferable for microcurrent stimulation therapy, and in particular, macular degeneration therapy.

Referring now to FIGS. 4a-4d, a method for treating visual system diseases, and in particular, a method for treating macular degeneration will be described. Specifically, to treat macular degeneration, a microcurrent stimulation therapy device, such as the one described above preferably is used. As mentioned above, in order to create a closed circuit for the microcurrent stimulation device, a brass cylinder or rod preferably is held in one hand of the patient, and a brass microcurrent stimulation probe with a shielded handle is applied to the patient by the therapist. The brass cylinder or rod conducts the electric current allowing the current to pass through the particular body part for therapy.

In accordance with one embodiment of the present invention, each eye that shows signs of macular degeneration is treated by providing a microcurrent through four points on the upper and four points on the lower eyelid for a total of eight points around the eye. FIG. 4a illustrates the

eight points around the eye which are stimulated and the preferred order of stimulation. For example, the stimulation preferably occurs in the order from point one to point eight. When stimulating the eyelid, the patient preferably looks away from the probe with eyes closed. This rolls the macula closer to the stimulation point, keeping the microcurrent from passing through dense eye structures, such as lens, iris and ciliary body, resulting in better microcurrent penetration into the macula region. The eight points around the eye are stimulated using a current between about 50 to about 350 microamps, and more preferably between about 150 and 250 microamps. In accordance with one preferred embodiment of the present invention, the current applied to the eyelid is brought up until the patient sees light flashes and/or feels the tinge of electricity. The current is then decreased so that the patient feels no discomfort. This is the preferred current level used for the therapy.

In accordance with a preferred embodiment of the present invention, each point around the eye is stimulated for about 8 to about 60 seconds, and more preferably for about 30 seconds, using a sweep wave signal. As discussed above, the sweep wave signal may comprise two independent sweep wave signals combined by an adder/buffer circuit. In accordance with this aspect of the present invention, one of the sweep wave signals preferably comprises a rectangular sweep wave signal having a peak-to-peak voltage of between about 10 to about 30 volts, and more preferably about 20 volts. In addition, the square or rectangular sweep wave signal preferably has a sweep wave frequency range of about 0 to about 400 Hz, and more preferably of about 0 to about 35 Hz; has a sweep time of between about 7 and about 60 seconds, and more preferably of about 15 seconds; and has a duty cycle of between about 20 and about 95 percent, and more preferably of about 75 percent. The other signal generator preferably provides a sweep wave signal having a lower peak-to-peak voltage than the first sweep wave signal. For example, the second sweep wave signal preferably has a peak-to-peak voltage of between about 0.1 to about 4 volts and more preferably about 1 volt, if needed. In addition, the second sweep wave signal preferably has a sweep wave frequency range of about 500 to about 2 MHz, and more preferably of about 500 to about 1.5 MHz; and a sweep time of between about 7 and about 60 seconds, and more preferably of about 15 seconds. The second sweep wave signal may comprise a sinusoidal wave form, a square wave form, a triangular wave form, a ramp wave form, a step wave form, or the like.

In accordance with another preferred embodiment of the present invention, the second signal comprises a non-swept or fixed frequency signal, rather than a swept or sweep wave signal. In accordance with this aspect of the invention, the non-swept wave signal may comprise a sinusoidal wave, a square or rectangular wave, a ramp wave, a step wave, or the like. Preferably, the non-swept wave signal has a peak or peak-to-peak voltage of between about 0.1 to about 4 volts, and more preferably about 1 volt. In addition, the fixed frequency of the non-swept wave signal preferably is in the range of about 500 Hz to 2 MHz, and more preferably in the range of about 500 Hz to 1.5 MHz.

In addition to stimulating points around the eye, the method for treating macular degeneration may include treating other acupuncture or pressure points on the body. For example, as shown in FIG. 4a, there are 2 points, A and B, on the forehead which can be used for microcurrent stimulation. In accordance with this aspect of the present invention, two probes preferably are attached to the frontal area of the forehead at points A and B, and a microcurrent

scan is applied to these points for about 10 to 20 minutes, and more preferably for about 15 minutes. In this manner, a relaxation mode of the therapy procedure is applied to the patient. That is, by attaching the electrodes to the forehead of the patient and applying a microcurrent to that location, the conductence of electricity in the head area is increased, thus helping relax the patient, as well as providing other therapeutic affects. For example, in this relaxation mode, some of the microcurrent is scattered toward the eye region, thus supplying additional microcurrent therapy to the eyes.

In addition, as illustrated in FIG. 4b, there are eight acupuncture or pressure points on the back of the neck which may be stimulated during macular degeneration therapy. In accordance with this aspect of the invention, each pressure point 1–8 is stimulated in ascending order for about 20 to about 60 seconds. Similarly, FIG. 4c shows 10 acupuncture or pressure points on the ear which also may be stimulated for macular degeneration therapy. As with the points around the eye and on the back of the neck, each point 1–10 on the ear is stimulated in ascending order for about 10 to about 30 seconds. Finally, FIG. 4d illustrates four pressure points on an arm which also may be stimulated in the same manner as with the eyes, neck and ears. In accordance with a preferred embodiment of the present invention, similar wave forms are used on the eyes, neck, ears and arms. However, in accordance with other preferred embodiments of the invention, different wave forms may be used on the different body parts, depending on the therapeutic effect of a particular wave form at a particular location.

In accordance with a preferred method for treating macular degeneration, patients initially are treated twice a day for 4 days and 3 times a week thereafter.

In conclusion, the present invention provides novel methods and apparatus for using microcurrent stimulation therapy to treat various physiological problems, such as pain, wounds and visual eye diseases. While a detailed description of presently preferred embodiments of the invention have been given above, various alternatives, modifications, and equivalents will be apparent to those skilled in the art. For example, while a particular circuit configuration is given for a sweep wave signal generator of the present invention, various other circuit configurations may be used; such as, digital signal processing circuits or digitally generated wave signal circuits. In addition, while one preferred method for treating macular degeneration is disclosed, other suitable methods may be used to treat macular degeneration, other eye diseases or other chronic problems such as pain and persistent sores. Thus, any number of sweep signal generator circuits and therapy methods may be used without varying from the spirit of the invention. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

What is claimed is:

1. A method for treating eye diseases using microcurrent stimulation therapy, comprising the steps of:

applying microcurrent proximate an eye, said microcurrent having an amplitude between about 50 microamps and 180 microamps and comprising a sweep wave microcurrent signal produced by a signal generator.

2. The method as recited in claim 1, wherein said stimulation therapy comprises therapy for treating visual system diseases, and said applying step comprises applying said microcurrent to an eyelid proximate an eye having a visual system disease.

3. The method as recited in claim 2, wherein said visual system disease is macular degeneration.

4. The method as recited in claim 2, wherein said visual system disease is retinitis pigmentosa.

5. The method as recited in claim 2, wherein said step of applying a microcurrent comprises applying the microcurrent to eight (8) points on said eyelid.

6. The method as recited in claim 5, wherein said microcurrent is applied to each of said eight (8) points for a period of time in the range of about 8 seconds to about 60 seconds.

7. The method as recited in claim 1, wherein said step of applying microcurrent to said body part further comprises applying a sweep wave microcurrent signal selected from the group of wave forms comprising sine wave, square wave, triangular wave, ramp wave, step wave, unipolar wave, bipolar wave, and window wave.

8. The method as recited in claim 1, further comprising the step of monitoring the current applied proximate said eye.

9. The method as recited in claim 1, further comprising the step of monitoring the signal wave form produced by said signal generator.

10. The method as recited in claim 1, further comprising the step of limiting the voltage signal applied proximate said eye.

11. The method as recited in claim 10, further comprising the step of monitoring the signal wave form after said step of limiting the voltage signal.

12. The method as recited in claim 1, wherein said microcurrent is in the range of about 50 microamps to about 200 microamps.

13. The method as recited in claim 1, involves combining two independent sweep wave signals to form said sweep wave signal.

14. The method as recited in claim 13, involves utilizing two different wave forms for said two independent sweep wave signals.

15. The method as recited in claim 1, involves combining a sweep wave signal and a non-sweep wave signal to form said sweep wave signal.

16. A method for treating visual system diseases using electrical stimulation, comprising the steps of:

generating a microcurrent signal comprising a sweep wave signal;

limiting the amplitude of said microcurrent signal using a current limiting circuit; and

applying said limited microcurrent signal to an eyelid proximate an eye having a visual system disease.

17. The method as recited in claim 16, wherein said visual system disease is macular degeneration.

18. The method as recited in claim 16, wherein said visual system disease is retinitis pigmentosa.

19. The method as recited in claim 16, wherein said step of applying said limited microcurrent signal to said body part further comprises applying a sweep wave microcurrent signal selected from the group of wave forms comprising sine wave, square wave, triangular wave, ramp wave, step wave, unipolar wave, bipolar wave, and window wave.

20. The method as recited in claim 16, further comprising the step of monitoring the current applied to the eyelid.

21. The method as recited in claim 16, further comprising the step of monitoring the signal wave form produced by said signal generator.

22. The method as recited in claim 16, further comprising the step of limiting the voltage signal applied to the eyelid.

23. The method as recited in claim 22, further comprising the step of monitoring the signal wave form after said step of limiting the voltage signal.

24. The method as recited in claim 16, wherein said step of applying a microcurrent comprises applying the microcurrent to eight (8) points on said eyelid.

25. The method as recited in claim 24, wherein said microcurrent is applied to each of said eight (8) points for a period of time in the range of about 8 seconds to about 60 seconds.

26. The method as recited in claim 16, wherein said microcurrent is in the range of about 50 microamps to about 200 microamps.

27. The method as recited in claim 16, involves combining two independent sweep wave signals to form said sweep wave signal.

28. The method as recited in claim 27, involves utilizing two different wave forms for said two independent sweep wave signals.

29. The method as recited in claim 16, involves combining a sweep wave signal and a non-sweep wave signal to form said sweep wave signal.

30. An apparatus for supplying an electrical signal to a body part in order to provide microcurrent stimulation therapy to said body part, comprising:

a sweep wave signal generator which generates a sweep wave signal;

a buffer/amplifier circuit which receives said sweep wave signal from said sweep wave signal generator, and buffers and amplifies said sweep wave signal, creating a buffered sweep wave signal;

a current limiting circuit which receives said buffered sweep wave signal from said buffer/amplifier circuit, and limits the amount of current supplied to said body part; and

a probe which applies the sweep wave signal from said current limiting circuit to said body part.

31. The apparatus as recited in claim 30, wherein said sweep wave signal generator comprises a first signal generator which generates a first signal, and a second signal generator which generates a second signal, at least one of said first and said second signals comprise a sweep wave signal and said apparatus further comprising a signal combining circuit which receives said first and said second signals from said first and said second generators and combines said first and said second signals into a single sweep wave signal.

32. The apparatus as recited in claim 31, wherein said signal combining circuit and said buffer/amplifier circuit are configured into a single circuit, comprising:

an operational amplifier having a positive input terminal, a negative input terminal and an output terminal;

said positive input terminal being connected to ground, said first signal being connected to said negative input terminal through a first resistor, said second signal being connected to said negative input terminal through a second resistor, and said output terminal being connected to said negative input terminal in a negative feedback loop through a variable resistor.

33. The apparatus as recited in claim 30, further comprising a voltage limiting circuit connected between said buffer/amplifier circuit and said current limiting circuit.

34. The apparatus as recited in claim 33, wherein said voltage limiting circuit comprises a variable resistor and a diode having an input terminal and an output terminal, said input terminal of said diode configured to receive said buffered sweep wave signal from said buffer/amplifier

circuit, and said variable resistor being connected between said input terminal of said diode and ground.

35. The apparatus as recited in claim 30, wherein said current limiting circuit comprises a current limiting resistor.

36. The apparatus as recited in claim 30, further comprising a current measuring device connected to the output of said current limiting circuit and adapted to measure the current output of said apparatus.

37. The apparatus as recited in claim 30, further comprising a spectrum analyzer configured to display the frequency spectrum of the buffered sweep wave from said buffer/amplifier circuit.

38. The apparatus as recited in claim 33, further comprising a spectrum analyzer configured to display the frequency spectrum of the sweep wave signal output from said voltage limiting circuit.

39. The apparatus as recited in claim 30, further comprising a data acquisition module for collecting data from said apparatus, said data to be used for microcurrent stimulation therapy analysis.

40. The apparatus as recited in claim 39, further comprising an interface for transferring data from said data acquisition module to a data acquisition and analysis system.

41. An apparatus for supplying an electrical signal to a body part in order to provide microcurrent stimulation therapy to said body part, comprising:

signal generating means for generating a first sweep wave signal;

amplifier means for buffering and amplifying said sweep wave signal from said first signal generating means, creating a buffered sweep wave signal;

current limiting means for limiting current supplied to said body part by said apparatus, said current limiting means configured to receive said buffered sweep wave signal from said amplifier means; and

signal application means for applying the sweep wave signal from said current limiting means to said body part.

42. The apparatus as recited in claim 41, wherein said signal generating means comprises first signal generating means for generating a first signal, and a second signal generating means for generating a second signal, at least one of said first and said second signals comprising a sweep wave signal, and said apparatus further comprising signal combining means for combining said first and said second signals from said first and said second signal generating means into a single sweep wave signal.

43. The apparatus as recited in claim 42 further comprising voltage limiting means connected between said amplifier means and said current limiting means for limiting the voltage amplitude of said buffered sweep wave signal.

44. The apparatus as recited in claim 42 further comprising current measuring means connected to the output of said current limiting means for measuring the current supplied to said body part.

45. The apparatus as recited in claim 42, further comprising data acquisition means for collecting data from said apparatus, said data to be used for microcurrent stimulation therapy analysis.

46. The apparatus as recited in claim 45, further comprising data transfer means for transferring data from said data acquisition means to a data acquisition and analysis system.